Thesis Project Portfolio

Design of an Insulin Glargine Manufacturing Plant to Increase Affordability and Accessibility of Diabetes Medication in the Sub-Saharan Region of Africa

Combatting the Disparities in Diabetes Healthcare Administration Among Minority Groups in America

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Executive Summary

Insulin is a life-saving medication that has been around for over 100 years; however, in today's world not all lives are being saved. For example, the technical research report investigates the limited accessibility and affordability of insulin in the sub-Saharan region of Africa. To meet the demand of this essential diabetes medication, the research proposes the design of an insulin-glargine manufacturing facility in Ethiopia to increase the accessibility and affordability of this medication in the sub-Saharan region of Africa. Across the Atlantic Ocean, obstacles for diabetic patients exist in the United States, as well. The STS research report examines how to combat the disparities in diabetes healthcare administration among minority groups in America. Both the technical and STS research reports aim to solve problems faced by diabetic patients in Africa and America, whether that is manufacturing and supplying insulin to people in need or eliminating barriers that prevent minority patients from getting the treatment they deserve.

The technical research report examines how diabetes has become a global epidemic, affecting over 420 million individuals worldwide. The accessibility and affordability of insulin remain major challenges across the globe, particularly in sub-Saharan Africa, where the limited access can result in life expectancies as low as one year for children with Type-11 Diabetes. Sub-Saharan Africa, which faces additional challenges such as infectious diseases, lack of diabetes education, and government constraints on patient treatment and insulin distribution, is particularly impacted by global supply chain and production issues of the medicine. To address these challenges, this project aims to design an insulin glargine manufacturing facility that is able to supply affordable insulin to 6 million people in sub-Saharan Africa. To meet this goal of supporting 25% of the diabetic population of Africa, 3 tonnes of insulin must be produced

annually. The insulin will be manufactured using a well-established biotechnological process involving genetically engineered *Escherichia coli* (*E. coli*) bacteria. The process encompasses various unit operations, including fermentation, cell harvesting, filtration, chromatography, concentration, sterilization, and purification.

As a result, the report includes a detailed upstream and downstream process that have been designed with an overall protein yield of 32.52% and will produce $2.79 * 10^6$ tonnes of insulin glargine per year. To reach our goal, 272 batches would need to be completed every year with each batch producing 10.24 kg of insulin glargine, thus meeting our target and supplying life-sustaining and affordable medication for the people of Africa. The upstream process is estimated to take 43.7 hours or 1.8 days, while the downstream process is estimated to take 346.5 hours or 14.4 days. With this process time, it would not be possible to have 272 batches made in a year, especially with planned maintenance, projected equipment deep-cleaning or replacement, and company holidays and shutdowns. Therefore, we decided to have additional incubators and lyophilizers, which were the rate limiting steps in our production schedule, in order to meet our goal in a timely manner thus rendering our project successful. After considering capital costs, operating costs, and selling each unit of our final product for $0.05, the plant will produce $3.8 billion in annual revenue, with an internal rate of return (IRR) of 60% over 15-20 years of operation based on a discounted cash flow analysis using a discount rate of 20%. Therefore, our project is deemed economically feasible and favorable.

The STS research report examines how although diabetes technology and insulin advancements have increased the level of treatment for diabetic patients in America, there are still disparities among the people who are able to afford and access the tools necessary to manage the disease. This research analyzes how disparities arose in the treatment and care of

underrepresented groups in America and how the American healthcare system can strive toward administering equal and unbiased care to all of its citizens. The aim of this research is to answer the question of why these disparities exist and how America's healthcare system can close the gaps caused by the disproportionate care administered to its underrepresented citizens. Evidence was collected through an analysis of previous research, current studies, and the personal experiences of healthcare professionals. The combined results from these sources was used to provide suggestions of how the healthcare system can improve and what steps can be taken for this progress. After analyzing numerous studies, reports, and interviews it is concluded that if the American healthcare system can follow the American Diabetes Association four-step approach to educate, negotiate, litigate,and legislate about diabetes discrimination, then the proper steps can be taken to eliminate medical bias in the United States.

As a result, this paper explored how disparities arose in the treatment and care of underrepresented groups in America and how the American healthcare system can strive toward administering equal and unbiased diabetes care to all of its citizens. The answer lies in the environmental, social and personal, and technological disproportionalities that segregate and discriminate against minority patients in the United States. Environmental factors affect diabetes bias in many different ways including but not limited to dietary habits, physical activity, perceived self-efficacy, and genetics. Technological advancements, new medications, and facility quality are also instruments in diabetes discrimination. The social aspect of diabetes discrimination include healthcare providers not having as many discussions and prescribing newer technologies, required insurance or clinical practice requirements related to diabetes self-management skills, and provider implicit racial bias. To overcome these discrepancies, people can look toward the environment, technology, and social factors to reverse their adverse

effects. For example, the government can put policies into place to reduce toxic waste disposal in our communities, including neighborhoods with low social-economic status or high minority populations. Technology can be created or tested for people of color and be advertised for these communities. As an example, clinical trials and access to these trials can be highlighted in ethnically diverse municipalities to increase the interest and involvement of minority communities in newly developed diabetes technology. Additionally, the social factor can be tackled by increased awareness and education for both the patient and the caregiver. Whether that includes diversity and inclusion modules, increased educational resources for diabetes management, or an increased interest of lobbyists and policymakers for this topic, social changes surrounding diabetes discrimination can be positive and improved. Because this is a multifaceted issue, orthogonal and integrative solutions are needed to fully resolve the disparities in diabetes care in the United States.

In conclusion, both the technical and STS research reports highlight current issues in diabetic health care and suggest tangible solutions to their respective problems. Whether that be supplying affordable insulin in sub-Saharan Africa to people who would otherwise not have access to this medication, or instituting environmental, technological, and social solutions to combat diabetes health care disparities felt by minority patients in America, both reports provide insightful information to help solve these problems. Most importantly, both reports highlight the importance of working together to increase the quality of life of diabetic patients around the world.